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13. ABSTRACT (Maximum 200 words) heat and Moisture Exchangers (HMEs) have been used for over 30 years for heat and moisture retention. Studies about bacteriostatic HMEs (SHMEs/NHMEs) have been conducted to assess their role in preventing bacterial transmission to the anesthesia breathing circuit (ABC); none have been done on anesthetized OR patients. This study adds to existing knowledge about the effect of HMEs in preventing transmission of bacteria with implications for cost reduction resulting from reuse of ABCs between patients. This quasi-experimental study involved adults (n=99) undergoing general endotracheal anesthesia for elective procedures. Subjects were randomly assigned to BHME or NHME groups. The appropriate HME was placed between the endotracheal tube (ETT) and ABC. At the conclusion of the case, the ETT and ABC were washed in a clinical laboratory. The wash was cultured to determine presence of bacteria. Cultures were described as positive or negative for Bacteria Colony-Forming Units (BCFUs); alpha level was $p < .05$, with a power of .80. The Chi square test revealed no statistically significant differences between groups in transmission of bacteria from ETT to Y-connector ($p = .485$). However, both groups showed statistically significant differences between presence of bacteria in ETTs and ABCs: BHME ($p < .005$) and NHME ($p < .005$). Neither MHE prevented contamination of the machine side of the circuit. These results support not reusing breathing circuits. Of 53 subjects in the NHME group, 28 had positive ETT cultures with 7 showing transmission to ABC. Of 46 subjects in the BHME group, 28 had positive ETT cultures with 9 showing transmission to ABC.				
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AN EVALUATION OF A BACTERIOSTATIC HEAT AND MOISTURE
EXCHANGER VS A NONBACTERIOSTATIC HEAT AND MOISTURE
EXCHANGER IN PREVENTING THE TRANSMISSION OF
BACTERIA COLONY-FORMING UNITS FROM THE
ENDOTRACHEAL TUBE TO THE ANESTHESIA
BREATHING CIRCUIT

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A Cluster Research Study
submitted in partial fulfillment
of the requirements for the degree of
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August, 1997

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ABSTRACT

Heat and Moisture Exchangers (HMEs) have been used for over 30 years for heat and moisture retention. Studies about bacteriostatic vs nonbacteriostatic HMEs (BHMEs/NHMEs) have been conducted to assess their role in preventing bacterial transmission to the anesthesia breathing circuit (ABC); none have been done on anesthetized OR patients. This study adds to existing knowledge about the effect of HMEs in preventing transmission of bacteria with implications for cost reduction resulting from reuse of ABCs between patients.

This quasi-experimental study involved adults (n=99) undergoing general endotracheal anesthesia for elective procedures. Subjects were randomly assigned to BHME or NHME groups. The appropriate HME was placed between the endotracheal tube (ETT) and ABC. At the conclusion of the case, the ETT and ABC were washed in a clinical laboratory. The wash was cultured to determine presence of bacteria. Cultures were described as positive or negative for Bacteria Colony-Forming Units (BCFUs); alpha level was $p < .05$, with a power of .80.

The Chi square test revealed no statistically significant differences between groups in transmission of bacteria from ETT to Y-connector ($p = .485$). However, both groups showed statistically significant differences between presence of bacteria in ETTs and ABCs: BHME ($p < .005$) and NHME ($p < .005$)

Neither HME prevented contamination of the machine side of the circuit. These results support not reusing breathing circuits. Of 53 subjects in the

NHME group, 28 had positive ETT cultures with 7 showing transmission to ABC. Of 46 subjects in the BHME group, 28 had positive ETT cultures with 9 showing transmission to ABC.

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The Committee for the
Protection of Human Subjects

NOTICE OF APPROVAL TO BEGIN RESEARCH

January 17, 1997

HSC-SN-97-001 - "An Evaluation of a Bacteriostatic Heat and Moisture Exchanger Versus a Nonbacteriostatic Heat and Moisture Exchanger in Preventing the Transmission of Bacterial Colony-Forming Units from the Endotracheal Tube to the Anesthesia Breathing Circuit"

P.I.: Captain Michael W. Neft, R.N., M.H.A.; et al

PROVISIONS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consents, etc.

APPROVED: At a Convened Meeting

APPROVAL DATE: January 17, 1997

EXPIRATION DATE: December 31, 1997

CHAIRPERSON: Anne Dougherty, M.D.

Subject to any provisions noted above, you may now begin this research.

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CHAPTER I

Introduction

The practice of using HMEs (heat moisture exchangers) as a method to control the transmission of bacteria to the anesthesia breathing circuit will be discussed in this chapter. The purpose, composition and clinical uses of HMEs and other bacterial filters will be included in this chapter.

Anesthesia breathing circuits, the inspiratory and expiratory circle tubing placed between the anesthetized patient and the anesthesia machine, have been implicated in the incidence of nosocomial infections (Leijten, Reijger, & Mouton, 1992). Concurrently, the increasing incidence of drug resistant strains of mycobacteria and other infective agents have heightened awareness of the role bacterial airflow filters and the potential HMEs may have in reducing infection. Although controversial, the current recommended standard of practice for reducing the risk of infection is the single use disposable breathing circuit with a bacterial airflow filter placed on the inspiratory or expiratory limb (American Association of Nurse Anesthetists, 1992).

Heat moisture exchangers have been in clinical use for over 30 years. Practitioners, based on individual experience and preference, use HMEs for the purpose of heat and moisture retention. Under general anesthesia, the heating and humidifying of inspiratory gases by the nose and pharynx are circumvented by the endotracheal tube. The inhalation of dry gases leads to tracheal damage and heat loss during anesthesia. The role of the HME in the anesthetic breathing

circuit is to function as an "artificial nose" to retain heat and moisture within the patient's respiratory system (Sessler, 1994 , p. 1374).

Bacteriostatic and nonbacteriostatic HMEs are currently available. The original design had multiple layers of wire gauze mesh or polished metal tubes placed in parallel at the condensation surface, but these lead to increased resistance to gas flow. Hedley and Allt-Graham (1992) stated that hygroscopic HME filters consisting of wool, foam, or paper-like material, often coated with moisture-retaining chemicals such as calcium chloride or lithium chloride, possess little resistance to gas flow because of their large pore size but may have limited filtration properties. The authors suggest the most efficient HME filters are paper-based.

Lee, Ford, Hunt, Ireland, and Swanson (1992) state an additional benefit of some new HMEs is the hydrophobic filter membranes which prevent bacterial movement past the filter. Filtration of bacteria is a valuable asset because it can potentially protect the breathing circuit from contamination. The filtering capabilities in bacteriostatic HMEs are characterized by their small pore size, approximately 0.3 microns, which is considered to be an effective barrier to the transmission of bacteria.

Laboratory studies not involving live subjects have utilized known bacterial challenges to a bacteriostatic HME filter at the Y-connector; findings support the practice of replacing the HME filter between each anesthetic patient and reusing the breathing circuit. These investigators reported a projected

\$18,418.00 per year savings with the use of an HME and the reuse of breathing circuits between patients and recommended clinically based studies (Berry & Nolte, 1991; Leijten et al., 1992). The only clinically based studies of the HME filter placed at the Y-connector have involved long-term ventilator patients in the critical care setting (Dreyfuss et al., 1995; Gallagher, Strangeways & Allt-Graham, 1987).

The anesthesia machine continues to be controversial as a source of pathogenic microorganisms and potential risk for infecting the anesthetized patient. Luttrupp and Berntman (1993) investigated the bacteriostatic capabilities of three different bacteriostatic HMEs under low gas flow conditions. They reported HME use had no bearing on the transmission of bacteria from the patient to the circle system and anesthesia machine because no pathological growth occurred with or without the use of a filter.

Gallagher et al. (1987) evaluated the use of the Pall Ultipor Breathing System Filter (BB50T) as an HME/bacterial filter. They evaluated two groups of ventilated critical care patients. The first group had an HME between the Y-connector and the patient. The second group had no HME. The HME group consisted of 75 patients, 16 of which were found to be colonized or infected with *Pseudomonas aeruginosa* (21.3%). The non-HME group consisted of 66 patients, 35 of which produced *Pseudomonas aeruginosa* (53%). They concluded that placement of an HME filter with bacterial filtration properties

between the Y-connector and the patient appeared to prevent contamination of the breathing system.

A study by Wygant, McGrory, Silka, and Smith (1994) , involving actual anesthesia patients, was designed to compare the effectiveness of placing bacterial filters on both the inspiratory and expiratory limbs with the placement of a single bacterial filter on the expiratory limb. The authors concluded that the HME filter used in-line at the Y-connector might be filtering bacteria because no bacteria were found at the culture sites on the inspiratory limb and the Y-piece of the anesthesia circle system. Interestingly, the particular HME filter lacked a bacteriostatic rating.

Statement of the Problem

A study to compare the effectiveness of a nonbacteriostatic HME with a bacteriostatic HME is lacking in the literature. If cultures reveal no growth with either HME there will be minimal risk of infection to the patient receiving either type of HME. If HMEs are changed between anesthetic cases, instead of changing breathing circuits, then a cost savings can be realized. This study compares the effectiveness of a bacteriostatic HME versus a nonbacteriostatic HME on the transmission of bacteria from the endotracheal tube to the anesthesia breathing circuit. No growth of bacteria at the Y-connector would indicate a lack of transmission from the endotracheal tube to the anesthesia breathing circuit.

Conceptual Framework

The conceptual framework for this study is the Nightingale Environmental Theory of Nursing (Figure 1) and the chain of infection model (Figure 2). The Nightingale Environmental Theory of Nursing proposes managing the physical environment so that nature can heal the patient (Nightingale, 1859/1946). The patient's central environment consists of his/her immediate physical setting, including social and psychological components. Cleanliness of the physical environment has a direct bearing on prevention of disease and mortality. Nosocomial infection remains a potential source of morbidity and mortality and causes extended hospitalizations. "Overall, nosocomial infections extend hospitalizations an average of four days per infection; approximately one percent of all nosocomial infections caused death and three percent contributed to death" (Weber, Rutala, Samsa, Wilson & Hoffmann, 1992, p. 192). Prevention of nosocomial infection is one way to provide a healing environment. The concept of the environment links Nightingale's theory to this research. The anesthesia circle system (the patient's breathing environment) is the focus of this study. This portion of the patient's environment will be tested for bacterial growth. The key point of the Nightingale model, the patient's condition and nature, is located in the center of the triangle (Torres, 1990). The patient's condition and nature are central to providing an environment that promotes healing or health.

A change in a healthy breathing environment potentially exposes the

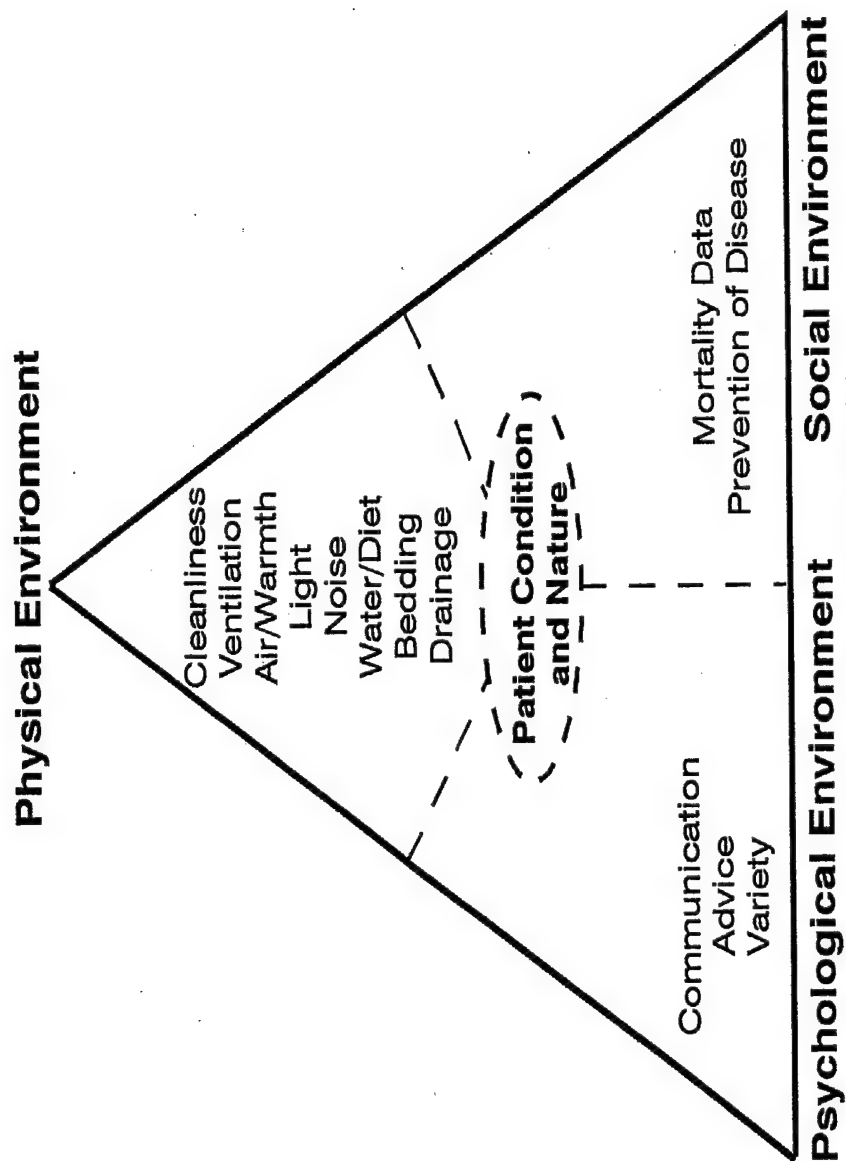


Figure 1. Nightingale Model

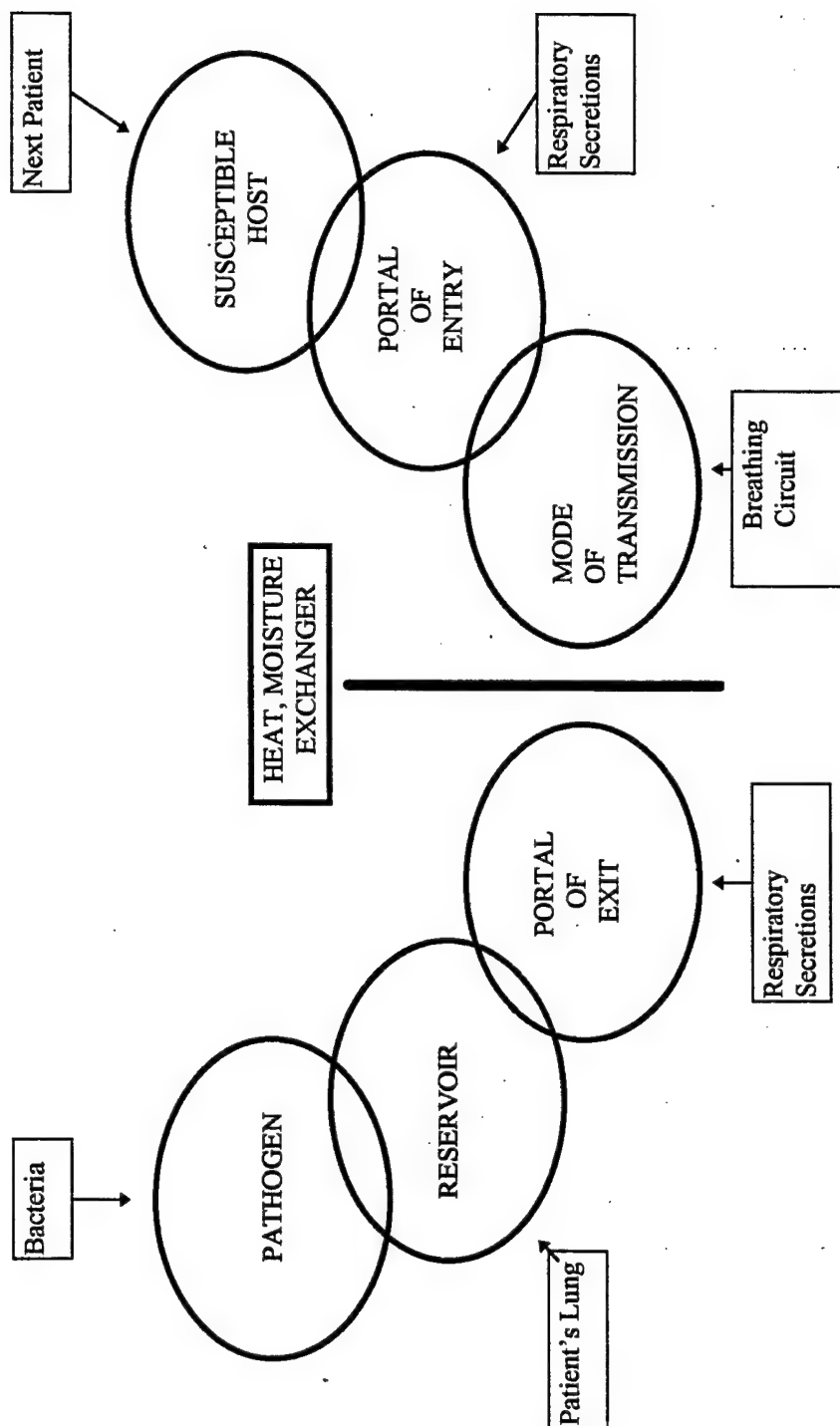


Figure 2. Chain of infection model

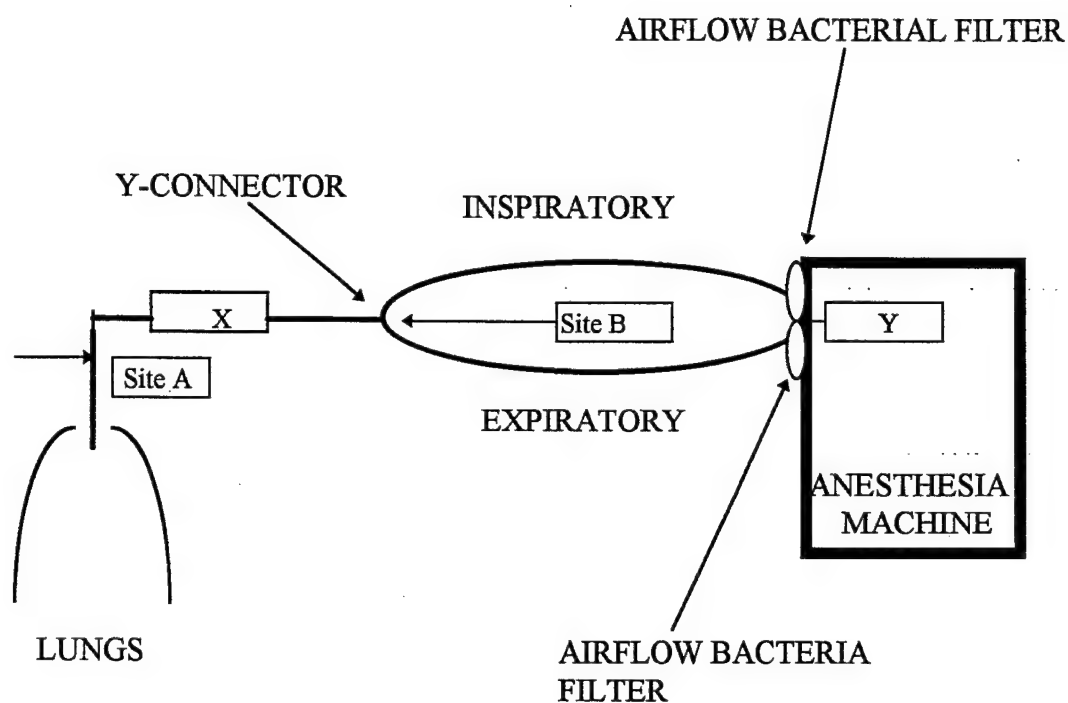
patient to infection. The chain of infection model illustrates the transmission of a pathogen to a susceptible host. Components of successful transmission include a pathogen, a reservoir, a portal of exit from the reservoir, a mode of transmission through the environment, a portal of entry into a new host, and a susceptible host (Barker & Black, 1993). The chain of infection in this study included pathogen growing in a patient's respiratory tract, transmitted via respiratory secretions. The pathogens can be transmitted via a droplet, aerosolization in the form of a mist, or air-borne mechanisms through the endotracheal tube and breathing circuit, and to the next patient receiving anesthesia using the same machine. This study investigated whether the chain of infection can be broken by placing a nonbacteriostatic HME or a bacteriostatic HME between the portal of exit (respiratory secretions) and the mode of transmission (breathing circuit).

Purpose

This quasi-experimental study evaluated the difference between a nonbacteriostatic HME and a bacteriostatic HME in preventing the movement of bacteria from the endotracheal tube to the Y-connector of the anesthesia breathing circuit. No specific guidelines for the use of HMEs regarding bacterial transmission in anesthesia practice exist at this time.

Definition of Terms

Figure 3 is a schematic of key components of the anesthesia circle system.



CULTURE SITES

- | | |
|---|----------------------------------|
| A | Endotracheal Tube |
| B | Y-connector of Breathing Circuit |

CIRCLE SYSTEM AND MACHINE PARTS

- | | |
|---|-----------------------|
| X | HME |
| Y | Carbon dioxide system |

Figure 3. Schematic of key components of the anesthesia circle system and culture sites.

Airflow bacterial filters. Conceptual definition: A filter, as distinguished from an HME, located on the inspiratory and expiratory limbs that prevents the transmission of bacteria between the anesthesia breathing circuit and the anesthesia machine.

Operational definition: King Vibrobac II filter, manufactured by King Systems Corporation, Noblesville, Indiana 46060, was the air-flow filter used for both sample groups. The Virobac II air-flow filter is rated by the company as being 99.985% effective in filtering bacteria and greater than 99.997% effective in filtering viruses. The filter weighs 31.1 grams and has a deadspace of 68 ml. The filter has a pore size of 0.3 microns and filters effectively for up to 72 hours.

Anesthesia breathing circuit. Conceptual definition: Plastic corrugated tubing connected to the anesthesia machine that serves as a conduit to deliver oxygen and anesthetic gases to the patient.

Operational definition: Product #82-1031230.00, DeRoyal Critical Care, Powell, Tennessee. Composed of machine cuff, mask elbow, bacterial/airflow filter, 2-60" 22mm corrugated hose, adult parallel "Y" and 3 liter standard breathing bag.

Bacterial colony-forming units (BCFU). Conceptual definition: The amount of bacterial microorganisms isolated from cultured endotracheal tubes and breathing circuits.

Operational definition: A BCFU is equal to 100 colonies per 0.5 milliliter of Stuart's solution. These results were reported as positive or negative.

Bacterial efficiency rating. Conceptual definition: The ability of an HME to filter bacteria as rated by its manufacturer.

Operational definition: Zero to 99.999%, based on laboratory tests by the manufacturer.

Bacteriostatic Heat and Moisture Exchanger. Conceptual definition: A device placed between the endotracheal tube and the Y-connector of a breathing circuit that purportedly filters bacteria and allows the retention of heat and moisture within the patient's respiratory system.

Operational definition: Sims HME model 2835 has a dead space of 44 milliliters, weighs 32 grams, has a resistance of 0.6 cm water at 30 L/minute, 1.0 cm water at 50 L/minute, and 1.6 cm water at 70 L/minute, with a filtration efficiency of 99.9+%.

Clean. Conceptual definition: Exempt of pathological microorganisms (Kozier & Erb, 1987).

Operational definition: The anesthesia breathing circuit and Virobac II airflow filters are clean in their packaging.

Coughing. Conceptual definition: A forceful, occasionally violent expiratory effort preceded by a preliminary inspiration (Thomas, 1989).

Operational definition: The presence or absence of coughing before or during extubation.

Culture Site A. Conceptual definition: Specific patient-side location from which specimen is obtained .

Operational definition: The endotracheal breathing tube, cut at the proximal margin of the cuff.

Culture Site B. Conceptual definition: Specific machine side location from which specimen is obtained.

Operational definition: The breathing circuit, clamped between the sixth ring from the Y-connector and cut on the side distal to the Y-connector. At the machine side, the circuit is clamped at the sixth ring from the airflow filters.

Endotracheal Tube (ETT). Conceptual definition: Tube inserted inside the trachea to provide the passage of gases to and from the lungs while preventing aspiration of foreign material into the trachea . Once placed in the trachea the cuff, which is approximately one inch wide and located at the distal end of the tube, is inflated.

Operational definition: The endotracheal tube. This device has an x-ray line and a 15 mm connector. It has a high volume, tapered, low pressure cuff.

Fresh Gas Flows. Conceptual definition: The gas supply from the anesthesia machine to the patient.

Operational definition: The liter per minute flow of gas from the anesthesia machine to the patient.

Nonbacteriostatic Heat and Moisture Exchanger. Conceptual definition: A device placed between the endotracheal tube and the Y-connector of a breathing circuit that allows the retention of heat and moisture within the patient's respiratory system with no purported bacterial filtration properties.

Operational definition: Thermovent 600 HME has a dead space of 11 milliliters, weighs 10 grams, and has a resistance of 1.9 cm water at 50 L/minute, and no bacterial filtration rating from manufacturer.

Position. Conceptual definition: The manner in which the body is arranged; its alignment.

Operational definition: The primary alignment the patient's body is placed in for most of the surgical procedure.

Smoking. Conceptual definition: The use of tobacco by inhalation.

Operational definition: Smoking of tobacco in cigarette, cigar form, or via pipe.

Sputum Production. Conceptual definition: Sputum is a substance produced by coughing or clearing of the throat. It may contain a variety of material from the respiratory tract. (Thomas, 1989)

Operational definition: The patient's sputum output in terms of presence or absence and color.

Sterile. Conceptual definition: Absence of living microorganisms (Thomas, 1989).

Operational definition: The stylets, HMEs, and endotracheal tubes are sterile.

Washings. Conceptual definition: A method of microbiological data collection.

Operational definition: The method utilized in this study of obtaining cultures from the ETTs and breathing circuits. In the washing method, a portion of the equipment to be cultured is clamped at two ends and a metered amount of Todd Hewitt broth is used to obtain a wet culture. At this point, the solution is plated and organism growth is monitored.

Hypotheses

There are three null hypotheses and three working hypotheses as follows:

1a. Null hypothesis: There is no difference between the number of positive cultures from the machine side of the bacteriostatic HME and the nonbacteriostatic HME.

1b. Working hypothesis: There is a difference between the number of positive cultures from the machine side of the bacteriostatic HME and the nonbacteriostatic HME.

2a. Null hypothesis: There is no difference between positive cultures from the patient side and the anesthesia machine side of the nonbacteriostatic HME.

2b. Working hypothesis: There is a difference between positive cultures from the patient side and the anesthesia machine side of the nonbacteriostatic HME.

3a. Null hypothesis: There is no difference between positive cultures from the patient side and the anesthesia machine side of the bacteriostatic HME.

3b. Working hypothesis: There is a difference between positive cultures from the patient side and the anesthesia machine side of the bacteriostatic HME.

Significance of the Problem

Anesthesia care providers can contribute to cost containment by investigating the efficacy of equipment and supplies typically used in practice. In this study the investigators compared the bacteriostatic capabilities of two different HMEs. If bacterial contamination rates are found to be no different between the bacteriostatic HME and the nonbacteriostatic HME, then a nonbacteriostatic HME could be used to prevent bacterial transmission from patient to anesthesia circle system. This practice may allow for the reuse of breathing circuits. The reuse of breathing circuits would reduce expenses (the cost of an average breathing circuit is \$13.00). Berry and Nolte (1991) calculated \$18,418.00 per year can be saved in a 14 room surgical suite by buying fewer breathing circuits. The results of this study may provide the practicing anesthetist with empirical data to support the use of an HME as a method to prevent contamination of the breathing circuit without compromising patient safety.

Findings of this study also have applicability to field training exercises and deployments. Ideal field expedient equipment should be compact, highly efficient, and reusable. According to Whitten (1993), "Equipment chosen for difficult environments should be lightweight, sturdy, simple to use, reliable, compact, standardized, easily repaired, and if possible, inexpensive" (p. 156). Condon and Lasater (1991) conducted an After Action Review (AAR) of Army anesthesia care providers involved in Operation Desert Shield/Desert Storm in

Southwest Asia. The observation was made that bulky anesthesia circuits required a lot of storage space. The recommendation of the anesthesia care providers was that circuits be reused and a reasonable number of circuits be available. With reuse, the circuits would need to be cleaned between patients. However, findings from this study may show the use of an HME between the patient and the Y-connector of the breathing circuit will eliminate the need to clean circuits between patients.

Assumptions

1. The machine delivering the anesthetic gases is free of bacterial contamination due to the use of bacteriostatic airflow filters placed on the inspiratory and expiratory limbs of the anesthesia breathing circuit.
2. The HME, Thermovent 600, is considered sterile in its packaging.
3. The breathing circuit and 2835 HME are considered clean in their packaging.
4. Microorganisms introduced into a subsequent patient's respiratory tract during general anesthesia may be infective.
5. Other reasons for contamination of the breathing circuit may be unrelated to the placement of an HME.
6. If breathing circuit washings are found to be negative, then no bacteria exists in the breathing circuit.

Limitations

1. The procedure used by the laboratory was to count the number of BCFUs at 24 hours thus eliminating growth that may appear after 24 hours.
2. This study did not test for viral or fungal growth.

CHAPTER II

Review of the Literature

Over the past 30 years the use of HMEs has evolved from only heat and moisture retention to other uses. The HME has been implicated in infection control and perhaps indirectly in cost containment. Bacteriostatic HMEs are thought to stop the transmission of bacteria from the endotracheal tube to the breathing circuit based on manufacturers' ratings. With the development of newer internal properties such as smaller pore size and pleated membranes, surface area and bacteriostatic efficiency are increased. If an HME is found to stop the transmission of bacteria, breathing circuits may not have to be changed between patients, thus achieving a cost savings. This chapter will present the consistencies and inconsistencies in the use and study of HMEs reported in the literature. A summary of these studies is shown in Table 1.

Infection control gained attention in anesthesia in the late 1970s. du Moulin and Sauberman (1977) studied the potential for the anesthesia machine and circle system to be sources of pulmonary infection and cross-infection. This research consisted of two parts. In the first part, six patients with gram-negative upper respiratory tract infections and nine uncolonized patients were given anesthetics. All anesthesia machines used in the study were identical and received no special treatment prior to the study. No significant differences existed between the cultures taken from the expiratory tubes from colonized or uncolonized patients. The investigators determined that regardless of prior upper respiratory colonization, patients did not contaminate the anesthesia machine with significant levels of bacteria (significant levels were not defined by the authors). The potential bactericidal quality of the soda lime was a proposed reason for the

Table 1

Summary of Studies in the Review of the Literature

Investigators	Method of Measurement	HME/Filter Used
Luttrupp & Berntman (1993)	Growth / No growth	1. Pall Ultipor BB50 2. Gibeck Humid-Vent 3. Pharma System Bact-HME
Dreyfus et al. (1995)	Colony-forming units	1. N61 Hygroscopic Dar Hygrobac II (HME) 2. N70 Bennett Cascades (Humidifier)
Leitjen, Reijger, & Mouton (1992)	Colony-forming units	1. Pall BB50T
Shelly, Bethune, & Latimer (1986)	Growth / No growth	1. Garthur 2. Portex Humid-Vent 3. Siemens-Elcoma Servo Humidifier 4. Engstrom-Edith 5. Pall Ultipor BB50
Hedley & Allt-Graham (1992)	Growth / No growth	1. Engstrom Edith 2. Pall BB50T 3. Dar Hygrobac 4. Intersurgical Filtatherm 5. Intersurgical Filtaguard
du Moulin & Saubermann (1977)	Growth / no growth	N/A
Gallagher, Strangeways, & Allt-Graham (1987)	Growth / No growth	1. Pall BB50T
Berry & Nolte (1991)	Growth / No growth	1. Pall HME Filter
Lee, Ford, Hunt, Ireland, & Swanson (1992)	Colony-forming unit	1. Darex Hygrobac 2. Gibeck Humid-Vent 3. Intersurgical Filtatherm 4. Intertech HME 225-2835-800 5. Pall Ultipor 6. DAR Mediplan Hygrobac

absence of bacteria. Soda lime consists of sodium hydroxide and calcium hydroxide which form an alkaline environment after interacting with carbon dioxide, and the alkaline environment prevents bacterial growth. The authors concluded that routine cleaning and sterilization procedures were sufficient to prevent cross-contamination and the use of bacterial filters and disposable circuits probably was not justified. In the second part, which was conducted in a laboratory without patients, the investigators disseminated a known bacteria through a circle system and anesthesia machine.

The machines, in both phases of the study, were cultured from six different locations before use: inspiratory port, expiratory port, reservoir bag port, inspiratory valve leaflet (underside), expiratory valve leaflet (underside), and the condensate at the bottom of the CO₂ absorber. Tubing, Y-connector, elbow joint, and the endotracheal tube were cultured after each trial. The tubing was cultured at 14 different arbitrary segments. A control group consisted of 18 corrugated tubes taken from unopened packages. The control tubing revealed bacteria similar to those noted in both colonized and uncolonized patients.

Nearly a decade later, Shelly, Bethune, and Latimer (1986) compared five commonly available HMEs: the Garthur, the Portex Humid-Vent, the Siemens-Elcoma Servo Humidifier, the Engstrom Edith and the Pall Ultipor BB50. The Pall Ultipor BB50 provides bacterial filtration related to its folded ceramic fiber element and its large hydrophobic surface area. The authors stated the Portex Humid-Vent has no antibacterial properties (which were undefined). The

Siemens-Elema Servo Humidifier has a fiberglass element and the Engstrom Edith contains a polypropylene fiber coated with lithium chloride and both contain antibacterial properties. The Garthur is an early condenser humidifier consisting of layers of wire mesh and contains no bacterial filtering properties. The investigators attempted to compare the efficiency of these HMEs to filter bacterial spores. Although this study labeled the Siemens-Elema Servo Humidifier, the Engstrom Edith, and the Pall Ultipor BB50 as having antibacterial properties, the definitions of these properties were not discussed.

An aerosol containing spores was passed through the HMEs and the residue collected on blood agar plates. Spores were used since they are more hardy than bacteria and these particular spores are approximately the same diameter as *Pseudomonas*. The plates were then incubated for 24 hours before counting the colonies. These researchers found the Pall BB50 filter was 99 percent effective in removing spores passing through it, while the other four were reported to have no measurable effect. No other statistical findings were reported for this study.

The following year Gallagher et al. (1987) studied mechanically ventilated patients in an Intensive Therapy Unit (ITU). The Pall Ultipor HME (BB50T), which is rated as 99.9% effective in preventing the passage of bacteria, was placed between the Y-connector and the endotracheal tube during the five month study period. Seventy-five patients were ventilated; 16 of these patients were colonized or infected with *Pseudomonas aeruginosa* prior to ventilation.

During a comparable five month period when HMEs were not used, 66 patients who required mechanical ventilation were admitted to the ITU. The respiratory tracts of 35 of these patients produced *Pseudomonas aeruginosa* prior to ventilation. The HMEs from the first group were cultured and airflow resistance was measured. Inspiratory and expiratory tubing was also cultured. The HME proved to be an effective barrier against pathogen movement when used at the Y-connector, as no *Pseudomonas aeruginosa* was isolated from the breathing system/ventilators. The researchers concluded that routine cleaning and sterilization of machines was not necessary, because the ventilator was effectively isolated from the patient by the HME. The strength of this study was the evaluation of an HME as a barrier to bacterial movement in the clinical setting. Unfortunately, there were no statistics reported for this research.

Dreyfuss et al. (1995) were concerned about the contribution of ventilator circuit bacterial contamination to the occurrence of ventilator-associated pneumonia in mechanically ventilated ICU patients. They conducted a prospective study describing whether bacteriostatic HMEs, placed between the Y-connector and the endotracheal tube, or a heated humidifier in-line circuit connection, location not specific, affected patient colonization and the incidence of nosocomial pneumonia in subjects who were mechanically ventilated for 48 hours.

Subjects were randomly placed into two groups: Group 1 used the hygroscopic DAR-Hygrobac II, n =61; and Group 2 used a heated humidifier,

n=70. Circuits were not changed and the duration of mechanical ventilation was identical for both groups during the study. Pneumonia was suspected during mechanical ventilation 48 hours after weaning whenever two criteria were present: new persistent infiltrates on chest radiograph (noted by a physician unaware of patient's group) or presence of macroscopically purulent tracheal aspirates. The occurrence of pneumonia was similar in both groups (6/61 and 8/70 in Groups 1 and 2, respectively, $p=0.8$). Interestingly, circuit contamination rate was markedly lower in Group 1 (the HME group) than in Group 2 at two different culture sites: 1) at the Y-connector (9/36 vs 20/40 for Group 1 and 2, respectively, $p<0.03$); and 2) at the expiratory tubing trap (3/36 vs 22/40 in Groups 1 and Groups 2, respectively, $p=0.001$). Bacterial colonization of the pharynx and trachea were similar for both groups.

This study revealed that the use of an HME at the Y-connector kept the circuits clean and free of condensate; however, no reduction in the incidence of pneumonia was found. Therefore, the investigators postulated that the occurrence of ventilator-associated pneumonia was not associated with colonization of the circuit, if usual maintenance precautions were followed. The authors did not specify the nature of these maintenance precautions. Moreover, these investigators discovered that while the use of heated humidifiers did increase colonization, it did not effect the incidence of ventilator-associated pneumonia from ventilator circuit bacterial contamination. Since there was no reduction in the incidence of pneumonia, the authors stated that circuits did not

have to be changed on each patient daily; however, they should continue to be changed between patients.

When cost containment became an issue, Berry and Nolte (1991) led the way by studying an anesthesia breathing circuit and a simulated lung to evaluate a Pall HME filter (specific model not identified), placed between the breathing circuit and simulated lung, in preventing bacterial contamination of the breathing circuit. This study consisted of four trials. In trial one, the system was inoculated in the inspiratory limb of the breathing circuit near the Y-connector. In trial two, the system was inoculated on the patient side of where the HME would normally have been located. An HME was not used in either of these trials. HMEs were used in trials three and four. In trial three the breathing circuit was inoculated on the inspiratory limb, close to the Y-connector. In trial four the breathing circuit was inoculated on the test lung side of the HME.

When the Pall HME Filter was placed between the test lung and the anesthesia breathing circuit, there were no positive bacterial cultures from samples taken from the machine side of the HME. Cultures taken from the test lung side of the Pall filter were positive for *Micrococcus luteus*. Filter location was based on the desire of the authors to establish support for not changing the anesthesia circle breathing tubing, Y-connector, reservoir bag, ventilator bellows and tubing between patients. During all trials a fresh gas flow of 2 liters per minute of oxygen were delivered.

Based on their results, Berry and Nolte (1991) recommended that a new Pall filter be used with all patients undergoing general anesthesia. This would permit the reuse of the anesthesia circle system, thus achieving a substantial cost savings. The study was not clinically focused, the actual HME filter was not named, and the sample size was not provided. Strengths of the study were that the researchers recommended further clinical studies with patients undergoing general anesthesia, two different sites were inoculated pre and post HME, and the fresh gas flow was standardized.

Leijten et al. (1992) echoed Berry and Nolte's recommendations after performing their own research in which a circle system was inoculated with *Serratia marcescens*, causing contamination throughout the system. Placement of a Pall BB50T HME bacterial/viral filter between a simulated patient and the Y-connector prevented transmission of all organisms to the system. Cultures obtained from several sites within the circle system, i.e. the Y-connector, expiratory and inspiratory tubing, water trap and reservoir bag, ranged from 4.84 to 6.20 colony forming units/ml. After the placement of the HME, contamination rates were zero at the same circle system locations. The authors concluded the interior of the circuit can become contaminated during use and contamination can be prevented by using a Pall filter between the patient and the breathing circuit. There were six different trials, each performed five times. There was no sample size noted.

Hedley and Allt-Graham (1992) compared microbial filtration properties and air flow resistance of five HME filters, none of which were specified as bacteriostatic. The five HMEs tested were the following: Engstrom Edith, Pall BB50T, DAR Hygrobac, Intersurgical Filtatherm, and Intersurgical Filtergard. The impetus for this study was stated: "Product information often quotes bacterial and viral removal efficiency data from the results of various types of aerosol challenge tests. However, performance may be different under wet conditions." (p. 418). Hygroscopic filters, composite filters, and pleated membrane filters were examined and compared in respect to hydrophobicity, liquid-borne and air-borne bacterial filtration efficiency, and airflow resistance after drug nebulization. The HME filters were placed between a simulated patient and Y-connector. The cultures were obtained from the breathing circuit side of the HME filter. The bacteria that passed through the test device (HME) was collected in an all-glass liquid impingement sampler containing sterile water, placed downstream from the HME. The investigators concluded the thin pleated membrane HME filter (Pall BB50T) provided better contamination control in wet and dry conditions and less airflow resistance in wet conditions and thus a wider margin of safety than either the hygroscopic filters or composite filters.

Lee et al. (1992) went further in the study of bacteriostatic HMEs by comparing the bacterial filtration efficiencies of six different HMEs. These were the Darex Hygrobac, DAR Hygrobac, Gibeck, Intersurgical, Intertech, and the

Pall Ultipor. The HMEs were evaluated on their ability to prevent the flow of airborne bacteria. An aerosol suspension of *Pseudomonas diminuta* was generated and passed through the six different HMEs. The test procedure ran for 15 minutes. On completion of the test, the water, collected by condensation on the distal side of the HME, was tested for *Pseudomonas diminuta* by serial dilution and by total filtration. Serial dilution is a quantifiable method to dilute the concentration of the bacterial sample to a smaller and more manageable number. The water in the liquid impingement sampler was filtered through a 0.22 μm membrane filter and the filter itself was cultured on blood agar plates. The cultures, recorded as growth or no growth, were incubated at 35°C for two days.

The researchers used a sample size of 10 for all HMEs except the Darex Hygrobac which had a sample size of five. The performance of the Darex Hygrobac was worse, $p < .05$, than the other five brands because the stock of filters was of an indeterminate age and one failed under test conditions. The one filter that failed did so because of a parting of its housing under testing. Due to the old stock and one failure, data collection was stopped on the Darex Hygrobac after five samples were collected. With the exception of the Darex HME, all the HMEs met their performance specification for bacterial filtration as detailed in the manufacturer's literature. This study found the mean bacterial filtration efficiency was as follows for each HME filter: DAR, Hygrobac, 99.9986%; Gibeck, 99.96%; Intersurgical, 99.99999%; Intertech, 99.991%; and Pall

Ultipor, 99.9998%. The Darex Hygrobac, which failed under testing, was 95.5% efficient. These results were reached based on aerosol filtration tests. No statistics were reported in this study.

Luttropp and Berntman (1993) analyzed prevention of bacterial contamination by HMEs from another perspective. Although no actual sample size was specified, they tested the significance of the location of the filter by placing HMEs between the endotracheal tube and the Y-connector, and between the circle system and the hose of an anesthesia machine ventilator. The HME filters were placed in this location because of the authors' concern about bacterial contamination of their new low-flow anesthesia system in which the circle was separated from the ventilator by a large bore, corrugated hose. These investigators quantified cultures as greater or less than 20 BCFUs. Positive cultures revealed microorganisms such as *Staphylococcus epidermidis*, *Propionibacterium acnes*, *Micoroccus* and *Bacillus* species; however, the investigators considered only *pseudomonas aeuroginosa* and *Staphlococcus aureus* as pathogenic cultures. Three series of cultures were evaluated. In the first series of cultures, three different filters (Pall Ultipor BB 50, Gibeck Humid-Vent, Pharma BACT-HME-collectively designated as Filter A) were cultured at both the patient side and the machine side. Filter A was located at the connection between the endotracheal tube and Y-piece. Nine of 55 cultures from the patient side of the A filters were positive, and all of fifty-five cultures from the machine side of the A filters were negative. Expiratory and inspiratory corrugated tubing

cultures revealed 17/27 positive cultures from the expiratory side, and 14/27 positive cultures from the inspiratory side. However, the organisms found in the tubing were identical to what was discovered in the control tubing.

The second series of cultures evaluated the effectiveness of the Pharma BACT-HME, designated as Filter B, placed between the circle system and the hose of an anesthesia machine ventilator. Cultures were taken from the expiratory port of the ventilator hose and on the circle system side of Filter B. Zero of 10 cultures sampled from the expiratory port of the ventilator were positive and one of 10 cultures obtained from the circle system side of Filter B revealed *Staphylococcus epidermidis*. In the third series of cultures, contamination of the ventilatory hose and expiratory port of the ventilator without Filters A and B was examined. Positive cultures were found in two of 10 cultures from the hose and one of 30 cultures from the expiratory port of the ventilator after one month of use without Filters A and B.

Luttropp and Berntman concluded that HMEs protect the anesthesia breathing circuit and isolate the anesthesia machine ventilator and hose from contamination with pathogens from the patient, thus prolonging decontamination service-interval of the anesthesia ventilator and hose. Maintenance costs were also decreased because of the reduced wear on the ventilators. However, without discussing the cause, the researchers discovered the lack of HME use in a third study group did not increase the incidence of

pathogenic growth of organisms in the hose or the expiratory port of the ventilator.

Wygant et al. (1994) studied bacterial airflow filters. They investigated the difference between one air-flow filter (on the expiratory limb) and the use of two air-flow filters (one on the inspiratory and one on the expiratory limb) in preventing the movement of bacteria through the anesthesia circle system when used on patients undergoing general endotracheal anesthesia. These investigators cultured the inspiratory limb of the anesthesia circle system proximal to the point where the corrugation begins, approximately 4.7 cm from the end of the tubing (i.e. the machine side of the inspiratory limb). The type of circle system tubing was not specified. All cultures revealed no growth after 48 hours. While the investigators admitted that the absence of growth from the cultures in their study was possibly attributable to inappropriate collection and culturing technique, they also postulated that the absence of growth may have been due to the use of an HME between the endotracheal tube and anesthesia breathing circuit. "Since no cultures were obtained proximal to the HME [patient side], we do not know if bacterial flow may have been stopped by the HME. The HME may have been functioning as a bacterial filter and could therefore have prevented movement of bacteria through the anesthesia circle system" (Wygant et al., p. 53). A flaw of this study was that the investigators did not culture the expiratory limb of the breathing circuit where bacteria may have been found.

Summary

Infection control became an issue for anesthesia practitioners in the 1970s. This provided the impetus for the evaluation of methods of preventing bacterial contamination of the anesthesia machine and circle system. As healthcare progressed into the next two decades, cost containment became an issue and anesthesia providers were faced with the need to limit their expenditures. Consequently, methods to formulate infection control standards and to save financial resources have been explored. However, a limitation in most studies conducted to date is that they were centered in the Intensive Care Unit on long-term ventilator patients and not centered in the operating room with patients undergoing general anesthesia. In order to truly evaluate the efficacy of a change in practice, i.e., changing HMEs between patients and not changing entire breathing circuits, clinical studies must now be conducted in the operating room setting under general anesthesia.

CHAPTER III

Methodology

The design used in this study is quasi-experimental. This chapter discusses population, sample and setting, instrumentation, procedure for data collection, protection of human subjects, study design, and proposed data analysis.

A pilot study was conducted consisting of two groups with eight patients in each group. The two groups had cultures obtained from six sites by culture swabbing: the endotracheal tube, the HME (4), and the Y-connector. Sample size and optimal culture sites in the definitive study were intended to be based on the results of the pilot study.

The pilot study proved to be inconclusive in that only three of the 16 endotracheal tubes, where positive cultures would be expected, were in fact positive. Additionally, no positive cultures were found at any other culture site. Discussion between the microbiologist, faculty, and the assistant chief of the Department of Clinical Investigations, centered on expected growth from an endotracheal tube of normal flora or pathological bacteria and the usual factors contributing to quality and quantity of sputum remaining in an endotracheal tube at the time of extubation. The method utilized in culturing the endotracheal tube in the pilot study did not reveal the expected growth. Without these data it would not be possible to illustrate transmission or lack of transmission to the machine side of the HME. Therefore, it was determined that a new method of investigating microorganisms within the endotracheal tube and breathing circuit

needed to be developed. It was decided that the endotracheal tubes, HMEs, breathing circuits and airflow filters of five patients would be submitted to the microbiology section of the Department of Clinical Investigations (DCI) for analysis via the washing method, in contrast to the previous swabbing method; this method was successful (producing positive cultures) and data collection proceeded.

Population, Sample, and Setting

The population consisted of patients scheduled for general endotracheal anesthesia at a 425-bed military teaching medical center in the Southwestern United States. The surgical suite had eight operating rooms in which approximately 5,000 surgical procedures are performed each year.

The required sample size for the pilot phase of the study was estimated using data from Dreyfuss et al. (1995). In that study, maximum numbers of colony forming units (CFU) collected from Y-connectors in patients on long-term mechanical ventilation with heat-moisture exchangers were reported. The maximum gram-positive cocci CFU was 100,000 and the minimum was zero. The distribution appeared to be skewed toward zero. The population standard deviation was estimated based on the following estimate for a skewed distribution (Snedecor & Cochran, 1989):

$$(\text{maximum}-\text{minimum})(.21) = \sigma$$

$$(100,000-0)(.21) = 21,000$$

Further calculations were made using this estimate of the standard deviation. During the pilot phase of the study, the investigators' goal was to characterize a 75% reduction in BCFU pre and post-HME, with 80% power and a significance level of $p < 0.05$. Fifteen subjects were required, based on the following equation for paired samples (Snedecor & Cochran, 1989):

$$n = (Z_{2\alpha} + Z_{\beta})^2 \sigma^2 / (\delta)^2$$

$$n = (7.9)(21,000)^2 / (15,750)^2$$

$$n = 14.04$$

$$n = 15$$

In the pilot study, the investigators gathered information about a nonbacteriostatic HME and a bacteriostatic HME. This was necessary because the researchers planned to compare the two filters directly in the definitive phase of study. To allow for a balanced design, eight of each type of filter was studied in the pilot study. Therefore, the total number of subjects in the pilot phase was 16. Data from the pilot phase were analyzed and the results were used to plan the definitive phase of the study. The sample size for the definitive portion of the study ($n = 92$) was arrived at based on the same statistical calculation as the pilot test.

The subjects in both phases of the study were selected from a convenience sample based on the following inclusion criteria:

1. Subjects were 18 years old or older.

2. Subjects required general endotracheal anesthesia for an elective procedure. Direct laryngoscopy and oral intubation with a conventional, cuffed ETT (i.e. no double lumen or nasotracheal tubes) was the only intubation method used.

3. Subjects did not have signs and symptoms of an upper respiratory tract infection two weeks prior to surgery.

The subjects in both phases of the study were assigned to one of two groups utilizing a randomization table. This table listed numbers representing the subjects chronologically, with the type of HME randomly assigned to each subject. As a surgical case was initiated by an investigator, the number representing that case on the randomization table was annotated so that the next investigator proceeded sequentially.

Instrumentation

The following instrumentation was utilized for the pilot study. Swabbed cultures were obtained from the ETT before extubation and at the Y connector before and after use, using the Baxter SIP® brand culturette. These culturettes contained Stuart's solution which kept the cultures viable for 72 hours.

Data Collection Sheet.

The data collection sheet was developed for use by the investigators to assure standard collection of data across investigators. The sheet included variables that could potentially impact growth found at culture sites and to ensure standardization of data collection. These included type of surgical

procedure, length of time HME was in use, fresh gas flow in liters per minute, patient position, smoking history, whether the subject coughed at time of extubation, and characteristics of secretions found in the endotracheal tube. The data collector was noted and HME type indicated. The variables were included on the data collection sheet to establish the existence of equivalence within the sample population. See appendix.

Procedure for Data Collection

During the definitive phase of the study, the following procedure was utilized by the investigators (see Figure 4 for culture sites used during the definitive phase of the study):

1. A new breathing circuit was attached to the anesthesia machine for each subject. The inspiratory and expiratory limbs were isolated from the machine using airflow filters.
2. The appropriate HME was selected based on the randomization tables created by DCI. It was placed in line when the circuit was attached to the machine. Low fresh gas flows, less than or equal to three liters per minute, were used on all study patients for the majority of the case. A sterile stylet was inserted into each endotracheal tube prior to intubation.
3. Upon extubation, the ETT exterior was wiped down with sterile gauze, placed in its original wrapper (saved since intubation), taped closed and packaged with the HME, breathing circuit, and airflow filters in a clean bag.

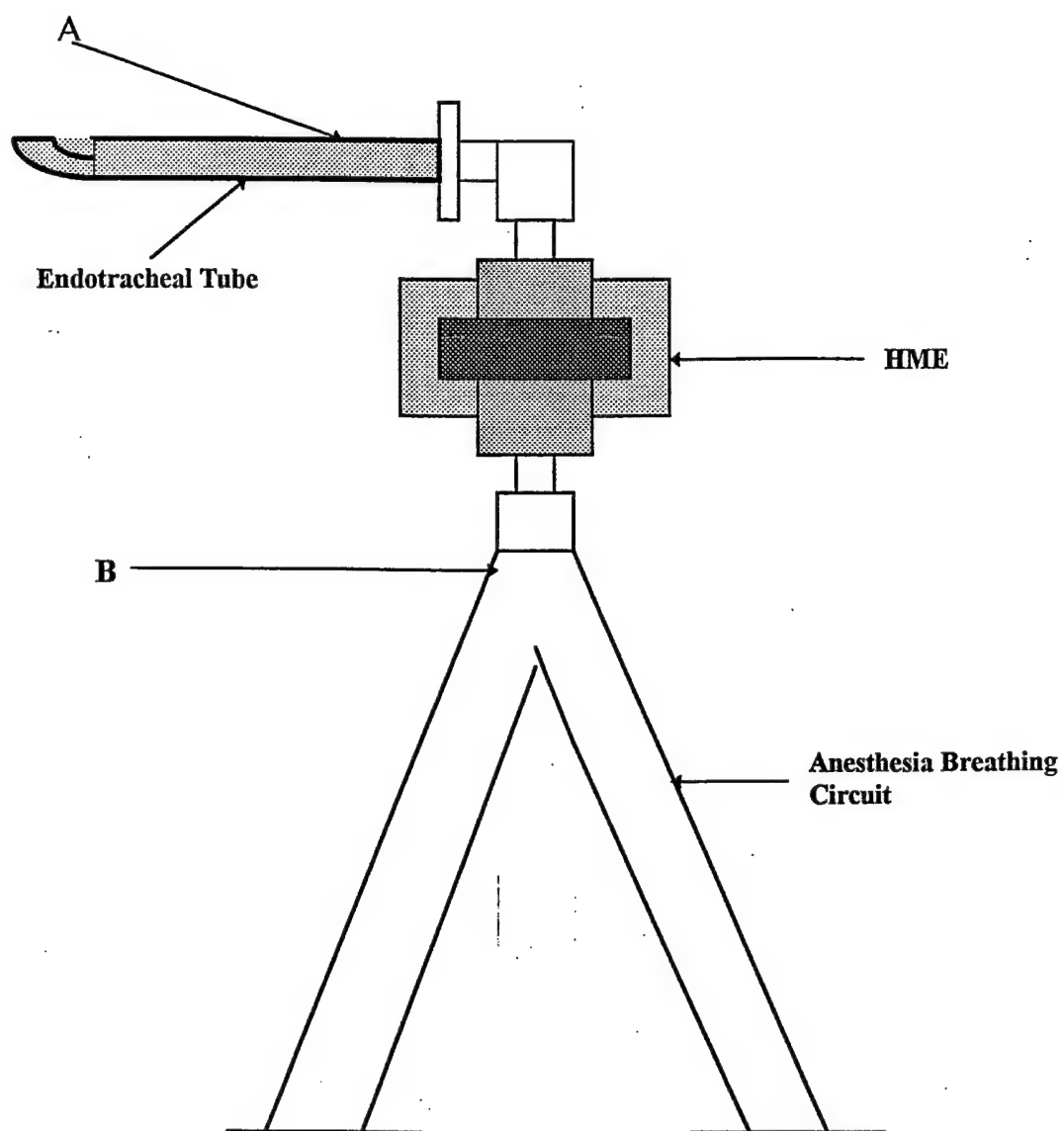


Figure 4. Diagram of endotracheal tube, HME, and anesthesia breathing circuit. Sites A and B represent location of culture sites.

These materials were then transported, within two hours, to DCI for analysis.

Once in DCI the study materials were processed in the following manner:

The following procedure was utilized by DCI for obtaining cultures from the endotracheal tube:

1. The ETT was received within a sterile, re-taped plastic bag; the tube is open at both ends when received within the bag.
2. The ETT was removed from the plastic bag with non-sterile gloves within the biohazard cabinet (laminar air-flow) and immediately clamped with a hemostat at the upper edge of the cuff (patient side of the tube).
3. Three ml of Todd-Hewitt broth is added aseptically to the tube and the tube was then clamped at the end opposite to the cuff at the 28cm mark.
4. The ETT was then rocked back and forth (tilted) at least five times to ensure that all inside surfaces are rinsed with broth.
5. The hemostat at the cuffed end was then removed first, making sure that the broth remains in the middle of the tube; the hemostat at the opposite end was then opened gradually to allow controlled drainage of the broth from the partially clamped end of the ETT (opposite end of the cuffed end) into a 15ml sterile conical plastic tube.
6. The conical tubes were then centrifuged at 2500rpm ($800 \times g$) for 15 minutes at room temperature.
7. Supernatant fluids were then removed by aspiration allowing approximately 100 ul of pellet and broth to remain in the conical tube.

8. Pellet was then resuspended using a 100 ul Eppendorf pipettor and the entire volume was transferred to a chocolate agar plate.

9. With a sterile (alcohol-flamed) glass rod spreader, the suspension was spread evenly over the entire surface of the chocolate agar plate.

10. The plates were inverted and incubated at 37°C in 5% CO₂ for approximately 24 hours.

11. Colonies as CFUs were counted and identified by appearance and gram stain.

The following procedure was utilized by DCI for obtaining cultures from the breathing circuit:

1. The anesthesia breathing circuit was received within a non-sterile, taped plastic bag (also containing ETT within its sterile, retaped bag); at the Y-connector in most cases (but not all cases), the HME filter was attached which closed off that end; at the other end of the tube there was a filter attached; for the tubes that were not closed at the Y-connector with an HME filter, there was a possibility that these tubes became contaminated during handling.

2. The anesthesia breathing circuit was removed from the plastic bag with non-sterile gloves within the biohazard cabinet (laminar air-flow)

3. The inspiration tube was clamped at the sixth ring from the Y-connector and then cut on the side of the clamp distal to the Y-connector.

4. At the machine end of the expiration tube, the tube was clamped at the sixth ring from the filter.

5. At the Y-connector opening, 100 ml of Todd-Hewitt broth was poured into the Y-connector opening so that the broth flows down the expiration tube.
6. As much broth as possible was allowed to flow down to the clamped end of the expiration tube; then with a rocking and twirling motion to insure all internal surface areas were rinsed, the broth was allowed to flow backward in the tube toward the Y-connector.
7. As the broth moved toward the Y-connector end, the tube was stretched to minimize trapping in the "accordion" rings; as the broth flowed through each stretched region of the tube, the tube was clamped to prevent backflow and each stretched region was cut off to allow for easier manipulation of the remaining tube.
8. Broth was drained into two 50 ml sterile plastic conical tubes; approximately 85-90 ml of the original 100 ml of broth was recovered.
9. The 50 ml conical tubes were then centrifuged at 2500 rpm (800 x g) for 15 minutes at room temperature.
10. Supernatant fluids were removed by aspiration allowing approximately 100-150 ul of pellet and broth to remain in each of the 50 ml conical tubes.
11. Pellets were resuspended and combined using a 100 ul Eppendorf pipettor and the entire volume (approximately 300 ul) was transferred to a chocolate agar plate.

12. With a sterile (alcohol flamed) glass rod spreader, the suspension was spread evenly over the entire surface of the chocolate agar plate.

13. Plates were inverted and incubated at 37°C in 5% CO₂ for approximately 24 hours.

14. Colonies as CFUs were counted and identified by appearance and gram stain.

Protection of Human Subjects

This proposal for use of human subjects was approved by the review boards of UT-HHSC and the Army Medical Center where the study was implemented.

Study Design

A quasi-experimental design was utilized in this study to measure the effect of a bacteriostatic versus nonbacteriostatic HME in preventing the transmission of bacteria found on the patient side to the machine side of both types of HMEs. Subjects were from a convenience sample and randomly assigned to one of two conditions, bacteriostatic or nonbacteriostatic HME. The manipulated variable in this study was the placement of one of two different HMEs.

This study incorporated a split-plot design with filter type as the main plot factor and sampling site as the sub-plot factor. Patients were randomized to filter type in permutations of two within blocks, using a random numbers table (Cochran & Cox, 1992). The five available operating rooms served as blocks. The

hypotheses were tested based on the number of positive cultures (ratio level data). The alpha level was set at 0.05. Cultures were obtained and the results of these cultures were described as positive or negative for bacterial growth per culture swab.

Potential threats to internal validity were variations in instrumentation and selection bias (LoBiondo-Wood & Haber, 1994). There were five different individuals collecting data. While a standardized method of collection was employed, individual variation could have occurred. However, the standardized data collection techniques were reviewed in group format to ensure accuracy between data collectors. Selection bias could have occurred with regard to the types of patients studied due to inability to control types of patients scheduled for surgery, presence or absence of preexisting disease states, or treatment with medications that may affect their pulmonary systems.

The effect of selection threatens external validity due to the unpredictable characteristics of the subjects (i.e. age, pre-existing disease states, and drug therapy). Thus, it may be difficult to generalize the findings of this study to a variety of patient groups.

Procedure for Data Analysis

Data for each sampling site within each subject were categorized as either positive or negative for colony-forming units. Subjects were also categorized based on smoking, coughing, position during surgery, HME type, presence or absence of sputum in the endotracheal tube, fresh gas flow measured in liters

per minute, machine type, number of subjects in each operating room and operation type. These categorical data were analyzed by Chi square using the FREQ procedure of SAS (SAS, 1990).

Time Line

November 1996	Executive Committee Review/Commander Approval
December 1996	University of Texas Health Science Center at Houston Clinical Investigations/Human Use Committee
November 1996	Data Collection Begins
March 1997	Abstract Preparation for AANA Poster Session
April 1997	Data Analysis
May 1997	Submission Deadline for AANA Poster Session Abstract
June 1997	Completion of Final Draft and Thesis Defense
July 1997	UTHSC-H Submission
August 1997	Poster Presentation at AANA National Convention
December 1997	Manuscript Submission (AANA Journal)
January 1998	Graduation

Budget

The equipment and supplies needed for the study were supplied by DCI. No additional supply cost related to the study was incurred. External sources were investigated for travel, poster preparation costs, and manuscript binding.

a. Travel for presentation(s)	\$ 2,000
b. Poster for presentation(s)	1,000
c. Manuscript binding	200

d. Postage for disseminating results	50
e. Reproduction costs	50
Total	\$ 3,250

CHAPTER IV

Analysis of Data

This research evaluated the difference between a nonbacteriostatic HME and a bacteriostatic HME in the prevention of bacterial contamination from the endotracheal tube to the Y-connector of the anesthesia breathing circuit.

Description of the Sample

The population sampled consisted of 99 adult patients scheduled for elective surgery under general endotracheal anesthesia at a 425 bed military teaching medical center in the Southwestern United States, excluding patients with symptoms of an upper respiratory infection within two weeks prior to their surgery. The subjects were assigned to one of two groups utilizing a randomization table. The randomization table indicated which type of HME, bacteriostatic or nonbacteriostatic, to be used on the subject. The randomization table was located in each of eight operating rooms.

There were 46 patients in the bacteriostatic HME group and 53 patients in the nonbacteriostatic HME group. Five patients were deleted from the original sample of 104 due to technical problems processing data in the DCI during the initial phases of the study.

The two HME groups were analyzed for equivalency so that any significant differences in the variable of interest, bacterial growth, could be attributed to the group of HME assignment. No statistically significant differences were found between the two groups on the following variables: operating room location,

smoking history, coughing during emergence, HME use time, fresh gas flow, data collector, patient position, and sputum production. Initially, the data were analyzed using T-tests to show significant differences between the two HME groups. However, when the DCI sampled the number of BCFUs in the ETTs and the anesthesia breathing circuits, the results showed "too numerous to count" results for the ETTs. Therefore, it was determined that results would be reported as "positive" or "negative" cultures for both the ETTs and breathing circuits, given the central research hypothesis that the bacteriostatic versus nonbacteriostatic HME would have a differential effect on the transmission of BCFUs from the patient to the anesthesia breathing circuit, to the anesthesia machine, and ultimately to the next patient through the anesthesia machine.

Table 2 illustrates the frequencies for variables analyzed for equivalency of samples. It notes how many subjects fell into each category analyzed. Fresh gas flows greater than three liters per minute was not added because the reader can assume that if fresh gas flow was not less than or equal to three liters per minute, it was greater than three liters per minute. Because of the variety of preoperative diagnoses, the column entitled "diagnosis" notes only what service the patient was from. The legend at the bottom of the table discusses scale used to define sputum characteristics. The "885A" under "machine type" is the federal government's deployment anesthesia machine, which is used for training purposes in its hospitals.

Table 2

Summary of Frequencies for Variables Analyzed for Equivalency of Samples

OR	Diagnosis	Smokers	Coughing	Machine Type	Sputum*	FGF ≤ 30pm	+ETT Cultures	Supine	Lith	Sitting	Prone
#1 = 6	Ortho = 6	Yes = 1 No = 3 ** = 2	Yes = 1 ** = 5	Ohmeda = 4 ** = 2	0 = 2 1 = 2 ** = 2	3 ** = 3	1	2	**	1	**
#2 = 8	GYN = 7 Plastics = 1	Yes = 1 No = 7	Yes = 2 No = 6	Ohmeda = 6 885A = 2	0 = 6 1 = 2	6 ** = 2	2	2	4	**	**
#3 = 13	Ortho = 2 ** = 11	Yes = 3 No = 10	Yes = 6 No = 7	Ohmeda = 13	0 = 5 1 = 5 2 = 3	12 ** = 1	6	4	**	**	**
#4 = 12	Gen Surg = 11 GYN = 1	Yes = 3 No = 9	Yes = 4 No = 2 ** = 6	Ohmeda = 12	0 = 1 1 = 6 2 = 4 ** = 1	12	8	8	2	**	**
#5 = 33	Gen Surg = 6 GYN = 2 Plastics = 22 ** = 3	Yes = 5 No = 28	Yes = 4 No = 20 ** = 9	Ohmeda = 30 885A = 3	0 = 16 1 = 10 2 = 6 ** = 1	28 ** = 5	18	28	3	**	**
#6 = 6	Gen Surg = 1 ENT = 5	Yes = 2 No = 4	Yes = 3 ** = 3	Ohmeda = 6	0 = 1 1 = 4 2 = 1	4	3	5	**	**	**
#7 = 12	Gen Surg = 10 Vasc = 2	Yes = 2 No = 10	Yes = 5 No = 4 ** = 3	Ohmeda = 12	0 = 8 1 = 4 2 = 0	12	12	9	**	**	**
#8 = 6	Neuro = 6	Yes = 2 No = 4	No = 3 ** = 3	Ohmeda = 6	0 = 2 1 = 2 2 = 2	6	3	3	0	0	3

* 0 = Water Vapor

1 = White or Clear

2 = Colored Secretions

** = Data Missing

Table 3 illustrates the frequencies of positive and negative cultures from the ETTs and breathing circuits by HME group, whether or not the patient currently smoked, presence or absence of coughing on emergence, and the presence or absence of sputum on emergence.

Findings

The purpose of this research was to determine the effectiveness of a bacteriostatic HME versus a nonbacteriostatic HME in preventing the transmission of bacteria from the ETT to the anesthesia breathing circuit. If the HMEs had proven to be effective, breathing circuits would not need to be changed between patients. However, breathing circuit cultures were positive in both HME groups. Based on these findings, anesthesia providers should continue to change breathing circuits between patients.

Of the 99 subjects sampled, the bacteriostatic HME group yielded 60.87% positive ETT cultures and 19.57% positive circuit cultures. The nonbacteriostatic HME group yielded 52.83% positive ETT cultures and 13.21% positive circuit cultures. See Figure 5.

Hypothesis 1

Null: There is no difference between the presence or absence of positive cultures from the machine side of the bacteriostatic HME and the nonbacteriostatic HME.

Research: There is a difference between the presence or absence of positive cultures from the machine side of the bacteriostatic HME and the

Table 3

Study Variables with Positive Versus Negative Cultures in the Endotracheal Tubes and Circuits

	N*	Positive ETT Cx	Negative ETT Cx	Positive Circuit Cx	Negative Circuit Cx
Smokers+	21 = 21.21%	16	5	3	18
NonSmokers	78 = 78.79%	40	38	13	65
BHME	46 = 46%	28	18	9	37
NBHME	53 = 53%	28	25	7	46
Coughing on Emergence+	25 = 36.76%	17	8	3	22
No coughing on Emergence	43 = 63.24%	23	20	9	34
Sputum+	56 = 57.15%	35	21	7	49
No Sputum	42 = 42.86%	21	21	9	33

*Sample size may not equal 99 due to missing data

+p. <.05

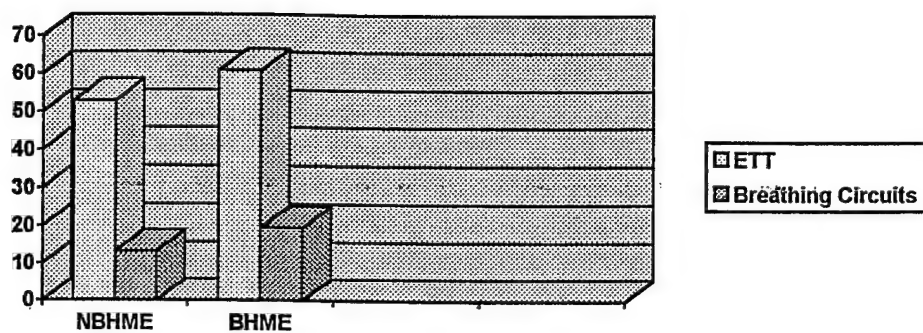


Figure 5. Percentage of Positive Endotracheal Tubes (ETT) and Breathing Circuit Cultures

nonbacteriostatic HME.

Results: There were 56 ETTs with positive cultures. Of this group, six of 28 total bacteriostatic HMEs had positive breathing circuit cultures. Four of 28 total nonbacteriostatic HMEs had positive breathing circuit cultures. The statistical test utilized was Chi-square and the level of significance was set at $p < 0.05$. The results were a Chi-square of 0.487, with $p = 0.485$.

Conclusion: The null hypothesis was accepted.

Hypothesis 2

Null: There is no difference between the presence or absence of positive cultures from the patient side and the anesthesia machine side in the nonbacteriostatic HME group.

Research: There is a difference between the presence or absence of positive cultures from the patient side and the anesthesia machine side in the nonbacteriostatic HME group.

Results: Of the 53 nonbacteriostatic HME group samples, there were 28 positive cultures on the patient side and 7 positive cultures on the anesthesia machine side. The Chi-square value was 18.81, with $p < 0.005$.

Conclusion: The research hypothesis was accepted.

Hypothesis 3

Null: There is no difference between the presence or absence of positive cultures from the patient side and the anesthesia machine side in the bacteriostatic HME group.

Research: There is a difference between the presence or absence of positive cultures from the patient side and the anesthesia machine side in the bacteriostatic HME group.

Results: Of the 46 bacteriostatic HME group samples, there were 28 positive cultures on the patient side and 9 positive cultures on the anesthesia machine side. The Chi-square for this analysis was 16.32, with $p < 0.005$.

Conclusions: The research hypothesis was accepted.

Summary

This research demonstrated that neither type of HME, bacteriostatic or nonbacteriostatic, is effective in preventing the transmission of BCFUs from the ETT to the anesthesia breathing circuit. Until further research shows otherwise, anesthesia providers should continue to change breathing circuits between every patient to minimize the risk of infection.

CHAPTER V

Discussion, Conclusions, Implications, and Recommendations

This research study evaluated the difference between a non-bacteriostatic HME and a bacteriostatic HME in preventing the movement of bacteria from the endotracheal tube to the anesthesia breathing circuit. Studies involving HMEs utilized in the operating room with actual patients were not found in the literature. This chapter includes discussion of the results, conclusions, findings, implications for nursing, and recommendations for further research.

Discussion

The objective of this study was to determine whether there were differences in bacterial contamination of the anesthesia breathing circuit when using a nonbacteriostatic HME as compared to a bacteriostatic HME placed between the endotracheal tube and the breathing circuit. The findings of this study showed the HME prevented transmission of most bacteria from the patient to the breathing circuit; however, no statistically significant difference in bacterial contamination of the breathing circuit existed between the bacteriostatic HME group and the nonbacteriostatic HME group.

The study design was quasi-experimental. A convenience sample was used in which the subject's group assignment was based on a table of randomization to one of two groups. The final sample was comprised of 99 adult subjects undergoing general endotracheal anesthesia. There were 46 subjects in the

bacteriostatic HME group and 53 subjects in the nonbacteriostatic HME group. The mean HME use time was 111 ± 11.5 minutes for the bacteriostatic HME and 123 ± 10.15 minutes for the nonbacteriostatic HME.

Hypothesis I stated that there would be a difference between the presence of positive cultures from the machine side of the bacteriostatic HME and the nonbacteriostatic HME groups. The mean number of positive cultures from the machine side of the bacteriostatic HME group was not significantly different from that cultured from the nonbacteriostatic HME group. There was no statistically significant difference between the groups using a Chi Square test with a $p=0.485$. The null hypothesis was accepted.

Hypothesis II stated that there would be a difference between the presence of positive cultures from the patient side and the anesthesia machine side of the nonbacteriostatic HME group. The number of positive cultures from the patient side (28 of 53) was greater than the number of positive cultures from the machine side (7 of 53) in the nonbacteriostatic HME group; a statistically significant difference was found ($p<0.005$) utilizing a Chi Square test and this hypothesis was accepted.

Hypothesis III stated that there would be a difference between the presence of positive cultures from the patient side and machine side in the bacteriostatic HME group. The number of positive cultures from the patient side (28 of 46) was greater than the number of positive cultures from the machine side (9 of 46)

in the bacteriostatic HME group; a statistically significant difference was found ($p < 0.005$) utilizing a Chi Square test and this hypothesis was accepted.

The conceptual framework for this research was based upon the Nightingale Environmental Theory of Nursing and the chain of infection model. Nightingale promotes cleanliness of the physical environment as having a direct bearing on the prevention of disease and mortality. Nosocomial infection remains a bacterial source of morbidity and mortality and has been responsible for prolonged hospitalizations. Preventing nosocomial infection promotes a healing environment. The chain of infection illustrates the transmission of a pathogen to a susceptible host. According to this model successful transmission of a pathogen requires a pathogen, reservoir, portal of exit, mode of transmission, portal of entry, and susceptible host. This research supports both the Nightingale Theory of Nursing and the chain of infection. The nonbacteriostatic HME group had 13.2% positive cultures in the breathing circuit and the bacteriostatic HME group had 19.5% positive cultures in the breathing circuit. Therefore, using an HME (bacteriostatic or nonbacteriostatic) blocked the majority of pathogens from entering the breathing circuit. This supports the chain of infection model in that the majority of pathogens were blocked from moving into the breathing circuit. However, the HME filters need to be improved upon so that pathogens would be completely prevented from moving into the breathing circuit. As Nightingale demonstrated in her theory, by decreasing environmental pathogens through cleanliness, our findings

demonstrate that pathogen movement was decreased with the placement of an HME. Therefore, a cleaner environment was created decreasing the likelihood of infection.

In 1977 du Moulin and Sauberman studied the potential for the anesthesia machine and circle system to be sources of pulmonary infection and cross-infection. One phase of the study involved culturing 18 breathing circuits directly from the package. The cultures revealed bacteria similar to those noted in both colonized and uncolonized patients. Theoretically, the breathing circuit may be colonized with bacteria prior to removal from its package. In four cases within our study, cultures were negative for the ETT but positive for the breathing circuit. Therefore, the breathing circuit could be a reservoir for infection. However, in our study the breathing circuits may not have been a reservoir for infection, because the ETTs cultures were negative. duMoulin and Sauberman also disseminated a known bacteria through an anesthesia machine and circle system and cultured these from six different locations. Although they cultured from six locations, those were spot cultures. Our research utilized the more conclusive method of culture washing.

Shelly et al.(1986) compared five commonly available HMEs and their ability to filter bacteria. They utilized an aerosol containing spores which was passed through the HMEs in the laboratory. Only one filter was found to be effective in removing spores exposed to it. This research went a step further by

utilizing actual patients in the operating room to support the findings of Shelly et al.

Mechanically ventilated patients in an Intensive Care Unit were studied by Gallagher et al. (1987). They evaluated the Pall Ultipor HME and found it to effectively isolate the patient from the ventilator. While these researchers did utilize actual patients in their study, they were long-term ventilator patients and not patients undergoing short-term ventilation for surgery.

In 1991 Berry and Nolte evaluated a Pall HME filter, placed between the breathing circuit and simulated lung, in preventing bacterial contamination of the breathing circuit. However, unlike this research study, they did not use living patients. Furthermore, while they recommended reuse of the breathing circuit with a Pall HME filter, this study could not recommend reuse of the breathing circuit with the Thermovent 600 nonbacteriostatic HME or the Sim model 2835 bacteriostatic HME.

Leijten et al. (1992) also performed research in the laboratory on a simulated patient to evaluate the bacterial filtration ability of the Pall HME filter. They found the Pall HME filter to be 100% effective in preventing the transmission of bacteria from the ETT throughout the circle system. This study evaluated the effectiveness of filters other than the Pall HME filter. Both the bacteriostatic HME ($p < 0.005$) and the nonbacteriostatic HME ($p < 0.005$) were found effective in filtering bacteria. However, due to the actual number of positive cultures grown from the breathing circuits (7 of 53 for the bacteriostatic

HME group, and 9 of 46 for the nonbacteriostatic HME group) reuse of the breathing circuit could not be recommended.

Lee et al. (1993) compared the bacterial filtration efficiencies of six different HMEs. Each HME was tested by exposing it to a bacterial aerosol suspension. They utilized a culture method of washing, similar to the one used in this study. With the exception of one, all filters met their performance specification for bacterial filtration as detailed in the manufacturer's literature.

Dreyfuss et al. (1995) also utilized mechanically ventilated Intensive Care Unit patients. They compared a bacteriostatic HME and a heated humidifier in-line circuit connection in the incidence of nosocomial pneumonia. Circuit contamination rates were markedly lower in the HME group but the occurrence of pneumonia was similar in both groups. These researchers concluded that, since there was no reduction in the incidence of pneumonia, circuits should be changed between patients. This study came to the same conclusion; that circuits be changed between patients.

Our research findings supported the results reported by other studies. duMoulin and Sauberman (1977) cultured 18 breathing circuits taken from unopened packages to reveal bacteria. The fact that in our study four cases had negative endotracheal cultures and positive circuit cultures may validate that aspect of the duMoulin and Sauberman (1977) study. Shelly et al. (1986) evaluated five HMEs and found only one to be 99 percent effective in removing spores passing through it. Neither HME utilized in our study was found to be

100 percent effective in filtering bacteria. However, tests of statistical significance showed that both HMEs were effective ($p < 0.005$).

Our study presents inconclusive data regarding recommendations made by other studies found in the literature review. This may be due to the fact that other studies focused on: (a) the Pall bacterial/viral HME (Gallagher et al., 1987; Berry & Nolte, 1991; Leijten et al., 1992); (b) mechanically ventilated Intensive Care patients (Gallagher et al., 1987; Dreyfuss et al., 1995); and (c) location of cultures or HME placement (Luttrupp & Berntman, 1993). Furthermore, every study in the literature review (except the study performed by Lee et al., 1993) utilized spot cultures instead of washings. Our study utilized washings.

Washings are more inclusive than spot cultures because they cover more surface area. Consequently, the results obtained from washings may be more accurate.

The strengths of this study were:

1. The data collection was performed solely by five researchers. All researchers, in group format, reviewed the protocol to be followed during data collection to ensure standardization. This added internal validity to the study.
2. All culture analysis was done by the same lab technician in DCI. This strengthened internal validity.
3. The individual performing the culturing was independent of the five researchers. All washings and subsequent cultures were performed by the lab technician in the DCI.

4. The comparison of two randomized groups, one utilizing a bacteriostatic HME and one utilizing a nonbacteriostatic HME, helped to provide internal validity.

5. A pilot study was conducted to insure adequate sampling technique. The method of washing was found to be most effective in detecting bacterial growth.

6. There was no statistically significant difference between the amount of time the bacteriostatic HME was in use and the amount of time the nonbacteriostatic HME was in use ($p=0.448$).

Noted weaknesses of this study were:

1. The potential for breaks in data collection technique due to multiple data collectors (five). Four cases exhibited negative cultures in the ETT and positive cultures in the breathing circuit. Causative factors could have been mishandling of samples by the investigators, lab technician, or both; or delivery of contaminated breathing circuits by the manufacturer.

2. The sample was restricted to adults eligible for care at a military hospital admitted for general endotracheal anesthesia.

3. The use of a double blinded study could have increased validity of the results. The researchers were not blinded to the type of HME used.

4. Variability in data analyzed with regard to coughing, smoking, and sputum was based on a number different than the $n=99$ used for this study. This was due to investigator error in annotation during data collection.

5. The type of anesthetic agent used may have affected the patient's ability or likelihood to cough. No data about whether opioids or inhalational agents were used was annotated on the Data Collection Worksheet.

6. Occasionally a patient may have required suctioning intraoperatively or prior to extubation which could have affected the amount of sputum found in the ETT after extubation.

7. Five breathing circuits were found to have fungus. This may have been caused by mishandling by an investigator or lab technician .

8. During initial data collection, HME location varied between investigators. Some placed the HME at the connection between the elbow and the ETT, while others placed the HME between the elbow and the breathing circuit. Subsequently all investigators placed the HME between the elbow and the breathing circuit.

9. All investigators may have used fresh gas flows greater than three liters per minute immediately prior to extubation.

10. Subjects 1 through 47 had a breathing circuit produced by a different manufacturer than subjects 48 through 99. This was due to a change of vendor by the purchasing agent in the anesthesia department.

Conclusions

The results of the study supported the following conclusions:

1. Positive cultures were obtained from breathing circuits in 13.2% of the cases where nonbacteriostatic HMEs were used. While this number was found

to be statistically significant ($p < 0.005$) most clinicians would consider it too high to tolerate with respect to reuse of the breathing circuit.

2. Positive cultures were obtained from breathing circuits in 19.57% of the cases where bacteriostatic HMEs were used. Again, while this number was found to be statistically significant ($p < 0.005$) most clinicians would consider it too high to recommend reuse of the breathing circuit.

3. Based on the results of this study, recommendations for reuse of the anesthesia breathing circuit while utilizing a bacteriostatic or nonbacteriostatic HME cannot be made. Although both filters were found to be statistically significant in their ability to filter bacteria, due to the occurrences of positive cultures in both groups, the current practice of using a new circuit for each patient should be continued.

4. Coughing and sputum production were found to be related with a $p = 0.001$. Smoking and sputum production were found to be related with a $p = 0.013$. Therefore patients who smoked produced more sputum, and patient who produced sputum coughed more. We examined this issue because we suspected that increased sputum production produced more positive cultures. The data analysis did not support this position with a $p = 0.379$.

Implications for Nursing

The following implications for nursing practice are derived from the results of this study:

1. Historically nursing has been involved in infection control and the prevention of nosocomial infection. This study demonstrated that the use of a bacteriostatic or nonbacteriostatic HME may not be beneficial in infection control and controlling the spread of infectious agents to patients. While both filters were found to be statistically significant in filtering bacteria, neither blocked 100% of bacteria. Therefore, broad conclusions cannot be made about the HME and the role it may play in infection control.

2. In the present health care environment, rising costs and the use of medical supplies are under scrutiny. Nursing administrators can cut costs by using less expensive nonbacteriostatic HMEs as opposed to more expensive bacteriostatic HMEs. Since both HMEs allowed the passage of bacteria from the ETT to the anesthesia breathing circuit neither can be used with the intent of preventing bacterial contamination of the breathing circuit. Therefore, either HME can be used for the purpose of retaining heat and moisture. If a less expensive nonbacteriostatic HME is chosen, instead of a more expensive bacteriostatic HME, then money can be saved. Based on the results of our study, each patient must have his own breathing circuit, therefore a large cost savings cannot be realized.

3. Field expediency cannot be improved upon based on the results of this research. Unfortunately, neither HME stopped bacterial transmission from the ETT to the breathing circuit. Consequently, we cannot recommend reuse of

breathing circuits. Therefore, it is still necessary to deploy with enough disposable circuits to complete the military mission.

Recommendations for Future Research

The following are recommended for further research:

1. HMEs from various manufacturers should be evaluated to determine if all HMEs function in the same manner as those utilized in this study.
2. HMEs should be evaluated for their efficacy in filtering viruses and fungus.
3. Breathing circuits should be evaluated for their contamination rates before opening and after cleaning. Perhaps, with further research, disposable breathing circuits could be reused after proper cleaning and decontamination.
4. HMEs of various construction, treated with different solutions, should be evaluated in an operating room environment with actual patients to determine the optimal design to be used.

APPENDIX

Data Collection Worksheet

Date: _____

Time: _____

Unique case number: _____

Diagnosis: _____

Surgical procedure: _____

HME use time: _____

(NOTE: starts with Turn Over To Surgeon [TOTS] time and ends with the beginning of surgical closure)

Anesthesia time: _____

Fresh Gas Flow (liters per minute): _____

Operating room number: _____

Patient Position: _____

Smoker: YES NO

Coughing: YES NO

ETT secretion characteristics: 0 = water vapor; 1 = clear, white; 2 = colored

Lab result: Bacteria colony forming units:

HME type: 1.) Thermovent 600 2.) Sims 2835 (Circle one)

Site A (endotracheal tube): _____

Site B (breathing circuit): _____

Student (data collector):

JG MN JH MF DJ (circle one)

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VITA

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VITA

John P. Hlavnicka was born in Breckenridge, Minnesota on March 17, 1952. After enlisted service in the U. S. Army, he graduated from the Williamsport Hospital School of Nursing, Williamsport, PA in 1984. He worked at Williamsport Hospital in critical care from 1984-1988. Upon receiving the BSN degree from Bloomsburg University in Bloomsburg, PA with honors in 1988, he entered the Westmorland-Latrobe School of Nurse Anesthesia, Greensburg, PA. Upon graduation from anesthesia school in 1990 he was employed at Westmorland Hospital as a staff nurse anesthetist. Upon commissioning he served in the USAR with the 318th Combat Support Hospital, Harrisburg, PA. Since returning to active duty in 1991, he has served at Ft. Belvoir, VA, 121st Evacuation Hospital , Seoul, Korea, Guantanamo Bay, Cuba (274th-FST airborne) and is currently completing the requirements for the MSN degree while serving at William Beaumont Army Medical Center. He is married to the former Lisa Reeves, also a Certified Registered Nurse Anesthetist. They reside in El Paso, TX.

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